IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

H. LUNDBECK A/S, et al.,	:	
	:	
Plaintiffs,	:	
v.	:	C.A. No. 18-88-LPS
	:	
APOTEX INC., et al.,	:	
	:	
Defendants.	:	

Jack B. Blumenfeld and Megan E. Dellinger, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, DE
George F. Pappas, Einar Stole, Christopher N. Sipes, Brianne Bharkhda, Priscilla G. Dodson, Alaina Whitt, and Allison Schmitt, COVINGTON & BURLING LLP, Washington, DC
Yiye Fu, COVINGTON & BURLING LLP, Palo Alto, CA

Attorneys for Plaintiffs

Kelly E. Farnan and Nicole K. Pedi, RICHARDS, LAYTON & FINGER, P.A., Wilmington, DE
Bradley C. Graveline, SHEPPARD MULLIN RICHTER & HAMPTON LLP, Chicago, IL
Jesse A. Salen, SHEPPARD MULLIN RICHTER & HAMPTON LLP, San Diego, CA
April E. Weisbruch, SHEPPARD MULLIN RICHTER & HAMPTON LLP, Washington, DC

Attorneys for Alembic Pharmaceuticals Limited, Alembic Global Holdings S/A, and Alembic Pharmaceuticals, Inc.

Adam W. Poff and Pilar G. Kraman, YOUNG CONAWAY STARGATT & TAYLOR, LLP, Wilmington, DE
Dennies Varughese, Robert C. Millonig, Daniel J. Ritterbeck, and Stephanie M. Nguyen, STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C., Washington, DC

Attorneys for Alkem Laboratories Ltd.

Karen L. Pascale and Robert M. Vrana, YOUNG CONAWAY STARGATT & TAYLOR LLP, Wilmington, DE
William L. Mentlik, Tedd W. Van Burskirk, Aaron S. Eckenthal, LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK, LLP, Westfield, NJ

Attorneys for Cipla Limited and Cipla USA Inc.

Kenneth L. Dorsney, MORRIS JAMES LLP, Wilmington, DE
Richard T. Ruzich, Stephen R. Auten, Ian Scott, and Philip Y. Kouyoumdjian, TAFT STETTINIUS & HOLLISTER LLP, Chicago IL

Attorneys for Apotex Corp., Apotex Inc. and Apotex Research Private Limited.

Kenneth L. Dorsney, MORRIS JAMES LLP, Wilmington, DE
Howard S. Suh and Nicholas P. Chiara, HOLLAND & KNIGHT LLP, New York, NY

Attorneys for Apicore US LLC.

Geoffrey Grivner, BUCHANAN INGERSOLL & ROONEY PC, Wilmington, DE
Matthew L. Fedowitz, Erin M. Dunston, and Mythili Markowski, BUCHANAN INGERSOLL & ROONEY PC, Alexandria, VA
Phillip L. Hirschhorn, BUCHANAN INGERSOLL & ROONEY PC, New York, NY

Attorneys for MSN Private Laboratories Limited, MSN Pharmaceuticals, Inc., and MSN Pharmachem Private Limited.

Kelly E. Farnan and Sara M. Metzler, RICHARDS, LAYTON & FINGER, P.A., Wilmington, DE
B. Jefferson Boggs, MERCHANT & GOULD PC, Alexandria, VA
Christopher J. Sorenson, MERCHANT & GOULD PC, Minneapolis, MN

Attorneys for Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc.

Dominick T. Gattuso, HEYMAN ENERIO GATTUSO & HIRZEL LLC, Wilmington, DE
Laura A. Lydigsen, Joshua E. Ney, and Judy K. He, BRINKS GILSON & LIONE, Chicago, IL

Attorneys for Sandoz Inc. and Lek Pharmaceuticals d.d.

John C. Phillips Jr., David A Bilson, and Megan C. Haney, PHILLIPS GOLDMAN MCLAUGHLIN & HALL, P.A., Wilmington, DE
Paul A. Braier, P. Branko Pejic, and Michael J. Fink, GREENBLUM & BERNSTEIN, P.L.C., Reston, VA

Attorneys for Unichem Laboratories, Limited.

Arthur G. Conolly III, CONNOLY GALLAGHER LLP, Wilmington, DE
H. Keeto Sabharwal, Ceric C.Y. Tan, and Yun Wei, PILLSBURY WINTRHOP SHAW PITTMAN LLP, Washington, DC

Attorneys for Torrent Pharmaceuticals Limited and Torrent Pharma Inc.

John C. Phillips Jr, David A. Bilson, and Megan C. Haney, PHILLIPS GOLDMAN MCLAUGHLIN & HALL, P.A, Wilmington, DE
Marc R. Wezowski, Don J. Mizerk, and David A. Gerasimow, HUSCH BLACKWELL LLP, Chicago, IL
Thomas P. Heneghan, HUSCH BLACKWELL LLP, Madison, WI
Daisy Manning, HUSCH BLACKWELL LLP, St. Louis, MO

Attorneys for Sigmapharm Laboratories, LLC.

MEMORANDUM OPINION

July 16, 2019
Wilmington, Delaware

STARK, U.S. District Judge:

Plaintiffs brought this suit against Defendants asserting infringement of U.S. Patent Nos. 8,772684 (the "'684 patent"), 8,969,355 (the "'355 patent"), 9,227,946 (the "'946 patent"), and 9,861,630 (the "'630 patent") (the "Crystalline Form Patents"), among others. Presently before the Court is the issue of claim construction. The parties[1] submitted technology tutorials (D.I. 213, 214), objections to such technology tutorials (D.I. 229, 231), claim construction briefs (D.I. 200, 201, 230, 232, 251, 253), exhibits (D.I. 201-1, 202-1, 230, 232, 251, 253), and expert declarations (D.I. 203, 204, 205, 206, 233). The Court held a claim construction hearing on May 29, 2019, at which both sides presented oral argument. (D.I. 263 ("Tr."))

I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (citation and internal quotation marks omitted). "[T]here is no magic formula or catechism for conducting claim construction." *Id.* at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

[1] The following defendants join in the proposed constructions of all disputed terms: Alembic, Alkem, Apicore, Apotex, Macleods, MSN, Sigmapharm, Torrent, and Unichem. (*See* D.I. 262-1 at 10) The following two defendants join in all proposed constructions, but do not join the argument that the term "alleviates/alleviating" is indefinite: Cipla and Sandoz. (*See id.*) The following four defendants do not join in any of the proposed constructions: Hetero, Lupin, Prinston, and Zydus. (*See id.*) Throughout this opinion, the term "Defendants" is intended to apply to only those defendants that join in the argument being discussed.

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). The patent "specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . . [b]ecause claim terms are normally used consistently throughout the patent." *Id.* (internal citation omitted).

It is likewise true that "[d]ifferences among claims can also be a useful guide . . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15 (internal citation omitted). This "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. It bears emphasis that "[e]ven

when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (alteration in original) (internal quotation marks omitted).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

"In some cases, . . . the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. "Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in

the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, while extrinsic evidence "may be useful to the court," it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

Finally, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (quoting *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

II. CONSTRUCTION OF DISPUTED TERMS

A. "characterized by an XRPD [pattern] as shown in [any of] FIG[S]..."[2]

Plaintiffs No construction necessary Alternatively, "identifiable by reference to an x-ray powder diffraction pattern as shown in [any of] FIG[S]..."
Defendants "having an XRPD pattern with all the peaks and corresponding relative intensities shown in the recited Figure[s]" Alternatively, the claim is indefinite
Court "identifiable by reference to an x-ray powder diffraction pattern as shown in [any of] FIG[S]..."

Claim 1 of the '684 patent is representative and claims a compound "in a crystalline form characterized by an XRPD pattern as shown in any of FIGS. 1-17." It is undisputed that each of Figures 1-17 in the '684 patent shows an XRPD pattern for a particular crystalline form, which corresponds to the specific examples set forth in the specification. (*See* D.I. 200 at 5; D.I. 232 at 4; *see also* '684 patent at 2:46-65) It also appears to be undisputed that it is scientifically impossible to consistently obtain identical XRPD patterns even for the same crystalline form, and that the specification and claims allow for experimental error.[3] (*See* D.I. 201 at 10; D.I. 230 at 4; D.I. 253 at 1; Tr. at 28-31) In fact, the specification expressly provides the maximum

[2] This term appears in claims 1 and 3 of the '684 patent, claims 2, 5, and 7 of the '355 patent, claim 2 of the '946 patent, and claims 3 and 6 of the '630 patent.

[3] While Defendants stated at oral argument that "experimental error is [not] part of the claims," Defendants also repeatedly argued that experimental error is specified in the claims and specification. (*See* Tr. at 28-31)

amount of experimental error permitted for the four major peak positions; claims 2 and 3 also specify a margin of experimental error. (*See* D.I. 230 at 4; '684 patent at 4:50-67 & cls. 2-3)[4]

Even though it appears that Defendants ultimately agree that experimental error is permitted, their proposed construction, which requires "all the peaks and corresponding relative intensities" shown in the Figures, suggests that an exact match to an XRPD pattern in the Figures is necessary for there to be infringement. (*See* D.I. 201 at 10; Tr. at 31-32) Defendants also fail to present any evidence supporting the relative intensities limitation in their proposed construction. (*See* Tr. at 46-48) As Plaintiffs note, the patents never mention relative intensities, and focus on peak positions. (*See* D.I. 201 at 10) As Plaintiffs' expert, Dr. Myerson, opines, there is considerable variability as to peak intensity, so a POSA[5] would commonly characterize crystalline forms without regard to relative intensity. (*See* D.I. 205 (Myerson Decl.) at 28) Dr. Myerson's opinion is consistent with the '684 patent and relevant literature, which also characterize XRPD patterns of the crystalline forms only by their peak positions. (*See* D.I. 201 at 9; '684 patent at 2:46-65)

Plaintiffs' construction is consistent with prior decisions in this Court and others. In *Eisai Co., Ltd. v. Glenmark Pharm., Ltd.*, 2015 WL 1228958, at *8-9 (D. Del. Mar. 17, 2015), where the claims and specification were silent on the matter of measurement error, the Court construed "characterized by" as "identifiable by reference to," relying on the agreement among

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[4] The Court is not persuaded that dependent claim 3 would end up being broader than claim 2 if Plaintiffs' construction is adopted, because claim 2 only refers to four specific peak positions whereas claim 3 refers to a corresponding XRPD graph that contains more characteristics than just the four identified peak positions. (*See* D.I. 200 at 4-5)

[5] Defendants do not challenge Plaintiffs' definition of a POSA and both parties agree that it does not impact claim construction. (*See* Tr. at 44-46)

the parties' experts that "XRPD was universally known at the pertinent time to be subject to measurement error." *Id.* (finding defendants' construction, which required an exact match, "too rigid"); *see also Kowa Co., Ltd. v. Amneal Pharm., LLC*, 2017 WL 10667089, at *38 (S.D.N.Y. Sept. 19, 2017) (finding that claim language "characteristic [XRPD] pattern with characteristic peaks" does not require exact match of all peaks and relative intensities); *AstraZeneca AB v. Dr. Reddy's Labs., Inc.*, 2013 WL 1847639, at *9 (D.N.J. May 1, 2013) (rejecting requirement for "exact match" of XRPD patterns as "too rigid" and construing "characterized by the following" as "identifiable by reference to"). Notably, Defendants agree that "identifiable by reference to" is synonymous with "characterized by" and that they have not pointed to any cases where the Court adopted their view. (*See* Tr. at 20, 33-34, 45)[6]

The Court is also not persuaded by Defendants' alternative view that the claim term is indefinite. A POSA would be able to assess the crystalline form and exemplary XRPD patterns provided in the patent and discern with reasonable certainty whether a particular crystalline form is characterized by a particular XRPD pattern. (*See* D.I. 205 (Myerson Decl. at 27))

Accordingly, the Court will adopt Plaintiffs' proposed construction.[7]

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[6] The Court is also not persuaded that the patent examiner already rejected such a construction. (*See* D.I. 200 at 7-8) During prosecution, the examiner rejected the word "approximately" in claims 2 and 3, because it has no accepted definition related to XRPD patterns, so it was replaced with experimental error measures to reflect the parameters of claims 2 and 3. (*See* D.I. 202 Ex. 2 at 3) The term at issue here does not raise the same concerns.

[7] Plaintiffs agreed not to object if Defendants' expert testifies at trial that "identifiable by reference to" requires an exact match. (*See* Tr. at 26)

B. "1-[2[(2,4-dimethylphenylsulfanyl)-phenyl]piperazine hydrobromide salt [alpha form, beta form, gamma form]"[8]

Plaintiffs a crystalline form of vortioxetine hydrobromide, referred to in the patent specification as ["alpha" / "beta" / "gamma"], that can be distinguished from other forms
Defendants vortioxetine hydrobromide salt crystalline form described in the specification as the [alpha / beta / gamma] form and having all characteristics assigned to the [alpha / beta / gamma] form in the specification
Court vortioxetine hydrobromide salt crystalline form described in the specification as the [alpha / beta / gamma] form and being identifiable by reference to the [alpha / beta / gamma] form in the specification

The parties dispute whether the claims require use of a particular set of analytical data from the patent's examples in order to identify each crystalline form of vortioxetine hydrobromide (i.e., alpha, beta, and gamma). Plaintiffs' proposed construction points to the specification's general references to each form, while Defendants propose that the forms are defined by the characteristics described in Examples 4b, 4d, 4f, 4h, and 4j of the '630 patent as well as Figures 2-5. (*See* D.I. 251 at 4; D.I. 253 at 6 n.6)

The Court agrees with Defendants that in the context of this patent "a POSA must look to the specification in order to identify and understand the scope of the claimed crystal form" (D.I. 230 at 13), but disagrees with Defendants regarding where a POSA would look. The examples in the patent on which Defendants rely are non-limiting examples of measurements that may result from specific analytical tests described in Examples 4a, 4c, 4e, 4g, and 4i. (*See* D.I. 232 at 9) For instance, Example 4b describes the alpha form "as prepared in example 4a," and Example 4a describes one analytical test that was performed on a sample, but both parties' experts agree that many different analytical tests may be performed to identify the same crystalline form (as

[8] This term appears in claims 1-7 of the '630 patent.

the same form may take on slightly varying characteristics depending on the preparation method). (*See* D.I. 232 at 9-10) Claims should not be limited to a patent's examples, unless the patentee demonstrated a clear intent to do so, *see Aria Diagnostics, Inc. v. Sequenom, Inc.*, 726 F.3d 1296, 1301 (Fed. Cir. 2013), and no such intent is evident here. Indeed, portions of the specification (such as a table) other than the examples on which Defendants rely also contain information a POSA could use to characterize and distinguish a given form. (*See* Tr. at 52-53, 68-69; '630 patent at 4:63-5:15) Defendants' construction would render superfluous the dependent claims, which add limitations with more specific characteristics (i.e., a particular XRPD pattern or particular XRPD peak positions). (*See* D.I. 201 at 15; D.I. 232 at 10; Tr. at 51-52; *see also*, *e.g.*, '630 patent, cls. 2-3)

The Court rejects Defendants' argument that the patentee's terminal disclaimer demonstrates that Plaintiffs acquiesced in the patent examiner's double-patenting rejection. (*See* D.I. 200 at 15-16; D.I. 232 at 11-12) *See Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (Fed. Cir. 1991) ("[T]he filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection."). Rather, the Court concludes, as did the patent examiner, that the claims at issue here are not identical to those of the prior patent, as the prior patent expressly incorporates limitations referring to particular XRPD characteristics while claim 1 of the '630 patent does not. (*See* D.I. 232 at 11)

The Court agrees with Plaintiffs that the claims are referring to the different forms as discussed in the patent rather than the forms with the specific characteristics in the examples. However, the Court finds that Plaintiffs' proposed "distinguished from other forms" language unhelpful. Accordingly, the Court will modify the construction (in a manner agreed-to by

Plaintiff at oral argument, *see* Tr. at 54-56), and consistent with the Court's resolution of the first dispute (i.e., "being identifiable by reference to"). The parties' dispute as to whether all of the characteristics must be met in order to qualify as a particular crystalline form is a factual dispute that will be addressed at the infringement stage.

C. "mixtures thereof"[9]

Plaintiffs No construction necessary Alternatively, "mixtures including vortioxetine hydrobromide salt alpha form, vortioxetine hydrobromide salt beta form, vortioxetine hydrobromide salt gamma form, vortioxetine hydrobromide salt hemihydrate, and vortioxetine hydrobromide salt ethyl acetate solvate"
Defendants "mixtures of only the foregoing listed forms"
Court "mixtures of only the foregoing listed forms"

The parties agree that claim 1 of the '630 patent recites a Markush group (*see* Tr. at 74, 77), as it lists specified alternatives in the form of: "selected from the group consisting of [A, B, C, D, E], and mixtures thereof." *See Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1357 (Fed. Cir. 2016). The Court agrees with Defendants that this language limits the components of the claimed mixtures. The claimed mixtures may not contain polymorphic forms not listed in the claim.

"Use of the transitional phrase 'consisting of' to set off a patent claim element creates a very strong presumption that that claim element is 'closed' and therefore 'excludes any elements, steps, or ingredients not specified in the claim." *Id.* at 1358 (quoting *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 239 F.3d 1239, 1245 (Fed. Cir. 2001)). Here, the Court agrees with Defendants that the term "consisting of" means that the Markush group "contains only what is

[9] This term appears in claim 1 of the '630 patent.

expressly set forth in the claim." *Id.* One of the items set forth in the group is "mixtures thereof." While the term "mixture" is often open-ended and "does not exclude additional, unnamed ingredients," *Mars, Inc. v. H.J. Heinz Co., L.P.*, 377 F.3d 1369, 1376 (Fed. Cir. 2004), in a Markush group – e.g., "A, B, and C, and mixtures thereof" – district courts have held that "mixtures thereof" allows "for mixtures of the listed Markush members" but prohibits other types of listed agents that are not in the Markush group, *see Galderma Labs. L.P. v. Teva Pharm. USA, Inc.*, 2018 WL 4290390, at *13 (D. Del. Sept. 7, 2018); *see also AstraZeneca Pharm. LP v. Handa Pharm., LLC*, 2010 WL4941431, at *4 (D.N.J. Nov. 30, 2010) (construing "mixtures thereof" to mean "a blend of two or more of the [types] recited in [the claim]").

Plaintiffs have not identified anything in the specification or prosecution history that "unmistakably manifest[s] an alternative meaning." *Multilayer*, 831 F.3d at 1359. The specification's discussion of polymorphic forms generally (beyond the five listed) does not demonstrate that the claims must include mixtures including forms other than the five listed. (*See* D.I. 200 at 16; D.I. 251 at 6) Nor has the Court been presented with extrinsic evidence supporting a conclusion that mixtures limited to the five forms recited would not make scientific sense.

Defendants concede that under their construction the mixture may contain excipients so long as the mixture does not include any unlisted forms of vortioxetine hydrobromide. (*See* Tr. at 87) The Court agrees.

D. "alleviates / alleviating"[10]

Plaintiffs No construction necessary Alternatively, "mitigates / mitigating"
Defendants Indefinite
Court "mitigates / mitigating"

Pursuant to 35 U.S.C. § 112, "a patent's claims, viewed in light of the specification and prosecution history, [must] inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014); *see also Cox Commc'ns, Inc. v. Sprint Commc'n Co. LP*, 838 F.3d 1224, 1231 (Fed. Cir. 2016) (noting relevant inquiry is "whether the 'claims,' not particular claim terms," inform one of scope with reasonable certainty). "Indefiniteness must be proven by clear and convincing evidence." *Sonix Tech. Co., Ltd. v. Publications Int'l, Ltd.*, 844 F.3d 1370, 1377 (Fed. Cir. 2017). Defendants have not met their burden.

Instead, the Court agrees with Plaintiffs that the plain and ordinary meaning of "alleviates" in the medical context is reducing the severity of symptoms. (*See* D.I. 232 at 16) This plain and ordinary meaning is used in the specification, which describes "alleviating" as "partially arrest[ing] the clinical manifestations" of MDD and "reliev[ing]" a symptom of MDD. (D.I. 201 at 18; '630 patent at 9:48-50, 9:66-10:1) Defendants' concern that a POSA would not know whether symptoms should be reduced or eliminated is without merit. The specification distinguishes "alleviate or relie[ve]" from "cure or eliminate." ('630 patent at 9:66-10:1)

[10] This term appears in claims 1, 2, 4, and 5 of the '946 patent and claims 1-7 of the '630 patent.

Dictionaries also clearly define the term as reducing symptoms, not requiring eliminating them entirely. (*See* D.I. 200 at 18-19; D.I. 201 at 19; D.I. 232 at 18-19)

Although there are several diagnostic scales that list differing symptoms for MDD, Defendants have not proven by clear and convincing evidence that a POSA's conclusion as to whether a patient's MDD symptoms were alleviated could actually come to a different conclusion based on which scale the POSA was reviewing. (*See* Tr. at 93-96, 99) Since "absolute precision" is not required, *see Nautilus*, 134 S. Ct. at 2129, quantitative measurements, temporal limitations, or specific methods of testing are not always required to render a claim not-indefinite. (*See* D.I. 200 at 19; D.I. 232 at 17-18) Rather, the record shows that "[c]linicians understand [MDD] symptoms and know how to evaluate whether the severity of one or more symptoms has been reduced in their patients." (D.I. 232 at 17-18 (citing evidence); *see also* D.I. 233 (Mattingly Declaration) at 7-10)

The Court will adopt Plaintiffs' proposed construction ("mitigates / mitigating") to clarify that the term requires only a reduction of symptoms.

III. CONCLUSION

The Court will construe the disputed terms as explained above. An appropriate Order follows.